MAR 2 8 2014

Hitachi Aloka Medical, Ltd.

K134016 Page 10f3

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR Part 807, Subpart E, Section 807.92.

21 CFR 807.92, Subsection a

1. Submitter's Information

Hitachi Aloka Medical, Ltd. 10 Fairfield Boulevard Wallingford, CT 06492-5903

Contact:

Angela Van Arsdale RA/QA Manager

Telephone: (203) 269-5088 Ext: 346

Fax Number: (203) 269-6075

Date Prepared: December 18, 2013

2. Device / Common / Classification Name / Classification / Product Code:

Device Proprietary Name - Arietta70 / AriettaS70/ AriettaV70 Diagnostic Ultrasound System

Common name - Diagnostic Ultrasound System and Transducers Classification name - System, Imaging, Pulsed Doppler, Ultrasonic

Classification: Class II

Product Code: 90-IYN 892.1550 Ultrasonic Pulsed Imaging System

90-IYO 892.1560 Ultrasonic Pulsed Echo Imaging System 90-ITX 892.1570 Diagnostic Ultrasound Transducer

3. Legally Marketed Predicate Device(s):

Hitachi HI VISION Ascendus Diagnostic Ultrasound Scanner [K110673] Hitachi Prosound F75 Diagnostic Ultrasound Scanner [K123828]

4. Device Description:

An ultrasound diagnostic system with the following features:

- o Ultrasound transducer(s) to generate the transmitted ultrasound energy and detect the reflected echoes
- Ultrasound transducer accessories (standard and optional) to maximize functional usage of transducer(s) in various modes of operation
- o A computer system to control the transducer and analyze the signals resulting from the reflected echoes
- o A video monitor with optional image recorder to display the computed image or derived Doppler data

5. Indication for Use:

The Hitachi Aloka Medical, Ltd. Arietta70/ AriettaS70 / AriettaV70 is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications.

The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real Time Tissue Elastography, and Real Time Virtual Sonography.

6. Comparison to predicate device:

The Hitachi Aloka Medical, Ltd. Arietta70 / AriettaS70 / AriettaV70 Diagnostic Ultrasound device is technically comparable and substantially equivalent to the HI VISION Ascendus Diagnostic Ultrasound Scanner [K110673] and Hitachi Prosound F75 Diagnostic Ultrasound Scanner [K123828]. The subject and predicate systems are track 3 systems that incorporate the same fundamental and scientific technologies. Both the subject and predicate device systems have the same intended use/indications for use.

	Subject	Pred	licates
Function	Hitachi Aloka Medical, Ltd. Arietta 70*/ Arietta S70*/ Arietta V70*	Hi Vision Ascendus K110673	Prosound F75 K123828
Color Flow	Х	X	X
TDI (Tissue Doppler Imaging)	X	X	X
Trapezoid	X	X	Х
Measurement function	х	х	Х
Dual Doppler	х	x	X
Marking assist display	X	X	NA
Real-time Doppler Auto Trace	X	X	X
Spatial Compound	X	X	x
FAM (Free Angular M-mode)	X	X	X
HI REZ/ AIP	X	x	X
EyeballEF	X	×	NA
DSD (Dynamic Slow motion Display)	x	NA	·X
CHI/ CHE	X	X	x
EFV (Extended Field of View)	X	X	X
Stress Echo	X	х	х
DICOM	x	x	x
DICOM SR	x	x	X
DICOM QR	x	x	x
Real-time Tissue Elastography	X	Х	x
RVS (Real-time Virtual Sonography)	X	x	NA
Picture in Picture	X	x	NA
Freehand 3D	X	X	X
Real-time 3D	X	X	X
3D STIC	X	x	X
Automated IMT measurement	х	х	X
Automated NT measurement	X	NA	X
ET (eTracking/ echo Tracking)	X	NA	X
FMD (Flow Mediated Dilatation)	X	NA .	x
WI (Wave Intensity)	X	NA	X

^{*}The Hitachi Arietta 70 / Arietta S70 / Arietta V70 are exactly the same with the exception of different color outer shell.

Hitachi Aloka Medical, Ltd.

21 CFR Part 807.92, Section b

1. Non-clinical Testing

No new hazards were identified with the subject device. The subject device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform to applicable medical device safety standards.

2. Clinical testing:

None required

3. Conclusions:

The Hitachi Aloka Medical, Ltd. Arietta70/ AriettaS70/ AriettaV70 Diagnostic Ultrasound scanner is substantially equivalent in safety and effectiveness to the predicate device;

- The subject and predicate device(s) are both indicated for diagnostic ultrasound imaging and fluid flow analysis.
- The subject and predicate device(s) have the same gray scale and Doppler capabilities.
- The subject and predicate device(s) have the same essential technology for imaging, Doppler functions, and signal processing.
- The subject and predicate device(s) have acoustic level below the Track 3 FDA limits.
- The subject and predicate device(s) are manufactured in accordance to FDA 21 CFR 820 Quality System Regulations.
- The subject and predicate device(s) are designed and manufactured to the same electrical and physical safety standards.
- The subject and predicate device(s) are manufactured with materials that have been tested in accordance to ISO 10993-1; all biocompatibility testing has been conducted in accordance to each component material characterization, type of body contact, and duration contact risk profile.
- The subject and predicate device(s) are designed to be re-usable and provide instructions for cleaning, disinfection, and sterilization in the Ultrasound system and transducer manuals.

END OF SUMMARY



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

March 28, 2014

Hitachi Aloka Medical, Ltd. (Hitachi Aloka Medical America) % Ms. Angela Van Arsdale RA/QA Manager 10 Fairfield Blvd. WALLINGFORD CT 06492-7502

Re: K134016

Trade/Device Name: Arietta70 / AriettaS70 / AriettaV70 Diagnostic Ultrasound Scanner

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX Dated: January 24, 2014 Received: January 29, 2014

Dear Ms. Van Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Arietta 70/Arietta S70/Arietta V70 Diagnostic Ultrasound Scanner, as described in your premarket notification:

Trans	ducer Model Number	
C251	C41V1	C41V
CC41R	R41R	C42T
L64	S12	VC34
VC41V	C41L47RP	UST-2265-2
UST-5293-5	UST-52126	C41
C42	C35	C22P
C25P	C41RP	C42K
L34	L441	L55
L46K	S31	S31KP
VL54	UST-2266-5	UST-5418

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement on last page.

		• •
510(k) Number (if known) K134016		
Device Name Hitachi Arietta70/AriettaS70/AriettaV70 Ultrasound Diagnostic Systematics (National Control of Con	em	
Indications for Use (Describe) The Hitachi Aloka Medical, Ltd. Arietta70/ AriettaS70 / AriettaV70 is for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Ceph. Gynecology, Urology and Laparoscopic clinical applications.	-operative, Fetal, Pediatri	c, Small Organ, Peripheral vessel,
The Modes of Operation are B mode, M mode, PW mode (Pulsed Wa Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Elastography, and Real Time Virtual Sonography.		
Type of Use (Select one or both, as applicable)		
☑ Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter	Use (21 CFR 801 Subpart C)
PLEASE DO NOT WRITE BELOW THIS LINE - CO.	NTINUE ON A SEPAR	ATE PAGE IF NEEDED.
FOR FDA US Concurrence of Center for Devices and Radiological Health (CDRH) (Si		
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of Information unless it displays a currently valid OMB number."

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	ical Application				M	lode of Operation	n	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CMD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P	Р	P	P	P
Fetal Imaging	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
& Other	Intra-operative (Spec.)	Ph	Pb	Pb		Ph	Ph	Pb
	Intra-operative (Neuro)	Р	Р	P	P	Р	Р	P
	Laparoscopic	P	Р	P		Р	Р	P
	Pediatric	P	Р	P	Р	P	P	P
	Small Organ (Spec)	Pd	Pd	Pd	Pd	Pd	Pd	PJ
	Neonatal Cephalic	P	P	P	P	P	Р	P
	Adult Cephalic	р	P	P	. Р	P	Р	p
	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph
	Trans-vaginal	P1`	Pf	Pf		Pi'	Pť	Pt'
	Trans-urethral						1	
	Trans-esoph. (non-Card.)	Р	P	P		P	P	P
	Musculo-skel. (Convent.)	Р	P	P		Р	P	Р
	Musculo-skel. (Superfic.)	P	P	P		P	P	Р
	Intra-luminal]	
	Other (spec.)							
	Cardiac Adult	Р	Р	Р	Р	Р	Р	Р
Cardiac	Cardiac Pediatric	p	μ	Ρ	Р	P	P	þ
	Trans-esophageal (card.)	Р	Р	Р	Р	Р	Р	P
	Other (spec.)							
Peripheral	Peripheral vessel	p	P	P	Р	P	P	P
Vessel	Other (spec.)	p	P	P		P	P	P

N = new indication. P = previously cleared in K123828 and K130308

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d". Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy

Subscript "e" Includes imaging for guidance of trans-rectal biopsy

Subscript "I" Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g" For pediatric patients

Subscript "h" Includes imaging for guidance of trans-rectal biopsy.

Prescription Use Only (Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k)_____

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^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

[•] Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta 870 / Arietta 870

Transducer: C251

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	cal Application		Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	M	CUVIS	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal	P	Р	P		P	Р	P			
Fetal Imaging	Abdominal	Pa	Pa	₽a		Pa	Pa	Pa			
& Other	Intra-operative (Spec.)										
	Intra-operative (Neuro)										
	Laparoscopic			<u> </u>			:				
	Pediatric	P	P	þ		p	l,	P			
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd			
	Neonatal Cephalic					•					
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal		<u> </u>								
	Trans-urethral										
	Trans-esoph, (non-Card.)			<u> </u>	ļ						
	Musculo-skel (Convent.)										
	Musculo-skel (Superfic)										
	Intra-luminal				ļ .						
	Other (spec)			<u></u>							
	Cardiae Adult										
Cardine	Cardiae Pediatric		<u> </u>	<u> </u>							
	Trans-esophageal (card)										
	Other (spec.)			<u> </u>							
Peripheral	Peripheral vessel										
Vessel	Other (spec.)		1		11						

N = new indication P = previously cleared in K110673

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "e" Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy,

Subscript "e" Includes imaging for guidance of trans-rectal biopsy Subscript "f" Includes imaging for guidance of trans-vaginal biopsy

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy

Prescription Use Only (Per 21 CFR 801, 109)

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^{*}Combination of each operating mode, B. M. PWD, and Color Doppler

^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C41V1

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	cal Application				M	ode of Operation)	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fctal	P	P	Р		P	Р	P
Fetal Imaging	Abdominal	Ť						
& Other	Intra-operative (Spec.)				}			
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric		L				l	
	Small Organ (Spec.)		l					
	Neonatal Cephalic			L				
	Adult Cephalic							·
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pſ	Pſ	Pſ		Pľ	Pr	Pſ
	Trans-urethral			ļ				
	Trans-esoph. (non-Card.)		<u></u>	ļ	<u> </u>			
	Musculo-skel. (Convent.)			<u> </u>				
	Musculo-skel. (Superfic.)			<u> </u>	<u> </u>		ļ	
	Intra-luminal		<u> </u>	↓	 			
	Other (spec.)			<u> </u>			ļ	
	Cardiac Adult				<u> </u>		ļ	
Cardiac	Cardiac Pediatric			<u> </u>	 		ļ	
	Trans-esophageal (card.)	_		ļ	-			
	Other (spec.)		<u> </u>	<u> </u>	<u> </u>		ļ	
Peripheral	Peripheral vessel		<u> </u>	 	↓		 	<u>-</u>
Vessel	Other (spec.) Gynecological	P	P	P		Р	l,	Р

N = new indication P = previously cleared in K130308

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d". Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy Subscript "f": Includes imaging for guidance of trans-vaginal biopsy

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

Prescription Use Only (Per 21 CFR 801.109)

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510(k)

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^{*}Combination of each operating mode, B, M, PWD, and Color Doppler

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C413

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clin	cal Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWI)	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic			Ī						
• • •	Fetal	P	Р	Р		P	P	Р		
Fetal Imaging	Abdominal									
& Other	Intra-operative (Spec.)									
	Intra-operative (Neuro.)			I						
	Laparoscopic				I I					
	Pediatric									
	Small Organ (Spec.)									
	Neonatal Cephalic		·							
	Adult Cephalic									
	Trans-rectal	Pe	Pe	Pe	\sqcup	Pe	Pe	Pe		
	Trans-vaginal	Pf	Pf	Pſ		PC	Pr	Pſ		
	Trans-urethral			1	ļl					
	Trans-esoph. (non-Card.)			<u> </u>	ļl		<u> </u>			
	Musculo-skel. (Convent.)			<u> </u>						
	Musculo-skel. (Superfic.)									
	Intra-luminal	<u> </u>		<u> </u>						
	Other (spec.)		l .		1			· · · · · · · · · · · · · · · · · · ·		
	Curdiac Adult									
Cardiae	Cardiac Pediatric		L	ļ	igsquare		ļ	L:		
	Trans-esophageal (card.)		<u> </u>	ļ—	 		ļ			
	Other (spec.)									
Peripheral	Peripheral vessel						ļ			
Vessel	Other (spec.) Gynecological	P	P	P	l	P	P	P		

N = new indication. P = previously cleared in K130308

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e". Includes imaging for guidance of trans-rectal biopsy. Subscript "f" Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g". For pediatric patients

Subscript "h" Includes imaging for guidance of trans-rectal biopsy

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^{*}Combination of each operating mode, B, M, PWD, and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography). 3D Imaging. Real Time Tissue Elastography, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: CC41R

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clin	ical Application				М	ode of Operation	n	
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic			1				
	Fetal	Р	P	P		Р	Р	. Р
Fetal Imaging	Abdominal							_
& Other	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic				l I			
	Adult Cephalic		L					
	Trans-rectal	Pe	Pc	Pe		Pe	Pe	Pe
	Trans-vaginol	Pť	Pf	Pf		Pf	Pi*	Pf
	Trans-urethral		L					
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)]				
	Musculn-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)		I					
•	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel			Ī				
Vessel	Other (spec.)							

N = new indication. P = previously cleared in K110673

*Combination of each operating mode, B. M. PWD, and Color Doppler.

Additional Comments:

Subscript "a" Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b" Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

Prescription Use Only (Per 21 CFR 801.109)

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^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: R41R

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	ical Application		Mode of Operation							
General (Track I only)	Specific (Tracks 1 & III)	B	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal									
Fetal Imaging	Abdominal									
& Other	Intra-operative (Spec)									
	Intra-operative (Neuro)			Ĭ						
	Laparoscopic									
	Pediatric		<u> </u>							
	Small Organ (Spec.)									
	Neonatal Cephalic		<u> </u>							
	Adult Cephalic				L1					
	Trans-rectal	P	P	P		P	P	þ		
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)		1	<u> </u>	<u> </u>					
	Musculo-skel. (Superfic.)				<u> </u>					
	Intra-luminal									
	Other (spec.)		<u> </u>	1						
	Cardiac Adult		1							
Cardiac	Cardiae Pediatric									
	Trans-esophageal (card.)			<u> </u>						
	Other (spec.)			<u> </u>			<u> </u>			
Peripherul	Peripheral vessel									
Vessel	Other (spec.)			I						

N = new indication. P = previously cleared in K130308

Additiona	l Comments
AUGULTOTIU	1 / 14 11 11 11 11 11 11 11 11 11 11 11 11

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). Subscript "a":

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c". Includes thyroid, parathyroid, breast, scrotum, and penis.

Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy: Subscript "d":

Includes imaging for guidance of trans-rectal biopsy Subscript "e": Subscript "f" Includes imaging for guidance of trans-vaginal hippsy

Subs

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script "g"; script "h"	For pediatric patients Includes imaging for guidance of trans-rectal biopsy.	
cription Use	Only (Per 21 CFR 801.109)	
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^{*}Combination of each operating mode, B, M, PWD, and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C42T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clin	ical Application				M	ode of Operation	1	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic]					•
-	Fetal							
Fetal Imaging	Abdominal							
& Other	Intra-operative (Spec.)	P	P	P		P	P	P
	Intra-operative (Neuro.)	_L						
	Laparoscopic		<u> </u>					
	Pediatric							
	Small Organ (Spec.)		<u> </u>	<u> </u>				
	Neonatal Cephalic .							
	Adult Cephalic							
	Trans-rectal			<u> </u>				
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							'
	Musculo-skel, (Convent.)		<u> </u>	<u> </u>				
	Musculo-skel, (Superfic.)		<u> </u>					
	Intra-luminal		ļ <u> </u>				<u> </u>	
	Other (spec.)		<u> </u>	<u> </u>				
	Cardiac Adult		l					
Cardiac	Cardiac Pediatric		L					
	Trans-esophageal (card.)						1	
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)		I				I	

N = new indication. P = previously cleared in K110673

Additional Comments:

Subscript "a": Includes imaging for guidance of percutuneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "c": Includes imaging for guidance of trans-rectal biopsy
Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B. M. PWD, and Color Doppler

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: L64

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	cal Application		Mode of Operation B M PWD CWD Color Combined* Other**								
General (Track I only)	Specific (Tracks 1 & III)	В	М	rwi	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal										
Fetal Imaging	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa			
& Other	Intra-operative (Spec.)			<u> </u>							
	Intra-operative (Neuro)										
	Laparoscopic					 	1				
	Pediatric	P	P	P		P	p	P			
	Small Organ (Spec.)	Pd	Pd	Pd	└	Pd	Pd	Pd			
	Neonatal Cephalic						<u> </u>				
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral				igsquare						
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)	P	P	P		P	P	Р			
	Musculo-skel. (Supertic.)	Р	P	P		P	Р	P			
	Intra-luminal						<u> </u>				
	Other (spec.)		i	<u> </u>							
	Cardiac Adult										
Cardiac	Cardiac Pediatric										
	Trans-esophageal (card.)			<u> </u>	igspace						
	Other (spec.)			1	<u> </u>						
Peripheral	Peripheral vessel	Р	Р	P		ρ	Р	P			
Vessel	Other (spec.)				<u> </u>						

N = new indication, P = previously cleared in K130308

Additional Comments:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). Subscript "a":

Includes imaging of organs and structures exposed during surgery Subscript "b":

(excluding neurosurgery and laparoscopic procedures).

Subscript "c" Includes thyroid, parathyroid, breast, scrotum, and penis

Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy Subscript "d"

Includes imaging for guidance of trans-rectal biopsy Subscript "e" Subscript "f". Includes imaging for guidance of trans-vaginal biopsy

For pediatric patients Subscript "g"

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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ription Use Only (Per 21 CFR 801	.109)
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^{*}Combination of each operating mode, B. M. PWD, and Color Doppler.

^{**}Amplitude Doppler (Cotor Flow Angiography). Real Time Tissue Elastography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: S

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clin	ical Application	.L			M	lode of Operation	3	
General (Track I only)	Specific (Tracks I & III)	В.	М	PWD	CWD	Cotor Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic			I				
	Fetal	Р	P	P	P	P	Р	P
Fetal linaging	Abdominal	Р	P	P	P	Р	P	P
& Other	Intra-operative (Spec.)						<u> </u>	
	Intra-operative (Neuro.)			<u> </u>				
	Laparoscopic							
	Pediatric	P	P	P	Р	P	Р	P
	Small Organ (Spec.)							
	Neonatal Cephalic			<u></u>				
	Adult Cephalic	Р	Р	P	Р	ļı	P	P
	Trans-rectal							
	Trans-vaginal			<u> </u>				
	Trans-urethral				<u> </u>			
	Trans-esoph. (non-Card)			<u> </u>	<u> </u>			
	Musculo-skel. (Convent.)			<u> </u>			ļ	
	Musculo-skel. (Superfic.)				<u> </u>			
	Intra-luminal			<u> </u>				
	Other (spec.)	·	<u> </u>	<u> </u>	<u> </u>			
	Cardiac Adult	Р	P	Р	P	Р	Р	Р
Cardiac	Cardiac Pediatric	Р	Р	P	P	Р	Р	P
	Trans-esophageal (card.)			1	1		<u> </u>	
_	Other (spec.)			<u> </u>				
Peripheral	Peripheral vessel	Р	P	P	P	Р	Р	Р
Vessel	Other (spec.)		ŀ	1	<u>1 </u>			

N = new indication, P = previously cleared in K)10673

*Combination of each operating mode, B. M. PWD, CWD and Color Doppler.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b" Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	cal Application	Mode of Operation R M PWD CWD Color Combined* Other**									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal	Р	. Р	IР		Р	Р	P			
Fetal Imaging	Abdominal	Р	P	Р		Р	Р	Р			
& Other	Intra-operative (Spec.)						-				
	Intra-operative (Neuro)						1				
	Laparoscopic			<u> </u>			<u> </u>				
	Pediatric	P	P	Р		P	P	Р			
	Small Organ (Spec.)	Р	Р	P		P	Р	Р			
	Neonatal Cephalic										
	Adult Cephalic						<u> </u>				
	Trans-rectal						}				
	Trans-vaginal			<u> </u>			1				
	Trans-urethral			1	ļ <u> </u>						
	Trans-esoph. (non-Card.)						1				
	Musculo-skel. (Convent.)			<u> </u>	1						
	Musculo-skel. (Superfic.)										
	Intra-luminal			1			<u> </u>				
	Other (spec.)			<u> </u>							
	Cardiac Adult										
Cardiac	Cardiac Pediatric										
	Trans-esophageal (card.)			ļ	11		ļ				
	Other (spec.)			1	ll		<u> </u>				
Peripheral	Peripheral vessel										
Vessel	Other (spec) Gynecological	P	P	P	1		I !				

N = new indication. P = previously cleared in K110673

Additional Comments:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). Subscript "a":

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Includes thyroid, parathyroid, breast, scrotum, and penis. Subscript "c":

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy. Includes imaging for guidance of trans-rectal hiopsy Subscript "e":

Includes imaging for guidance of trans-vaginal biopsy. Subscript "1":

Subscript "g": For pediatric patients

Includes imaging for guidance of trans-rectal biopsy. Subscript "h".

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ption (38 Only [Per 21 CPR 301,109]	
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^{*}Combination of each operating mode, B, M, PWD, and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: VC41V

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal	Р	P	P		P	Р	P			
Fetal Imaging	Abdominal			<u> </u>							
& Other	Intra-operative (Spec.)										
	Intra-operative (Neuro.)		<u>L</u>								
	Laparoscopic		<u> </u>		<u> </u>						
	Pediatric										
	Small Organ (Spec.)			l							
	Neonatal Cephalic]	I						
	Adult Cephalic]							
	Trans-rectal										
	Trans-vaginal	P	P	Р		p	Р	P			
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)										
	Intra-luminal			1							
	Other (spec.)]							
	Cardiac Adult			I]						
Cardiac	Cardiac Pediatric										
	Trans-esophageal (card.)										
	Other (spec.)										
Peripheral	Peripheral vessel		Į -								
Vessel	Other (spec.) Gynecological	Р	Р	P		P	. Р	Р			

N = new indication. P = previously cleared in K123828

Additional Comments:

Subscript "a" Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b" Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c" Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d" Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e". Includes imaging for guidance of trans-rectal biopsy. Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B, M, PWD, and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography), 4D Imaging.

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C41L47RP

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	cal Application				M	lode of Operation)	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	l'etal						I	
Fetal Imaging	Abdominal			1				
& Other	Intra-operative (Spec.)				I			
	Intra-operative (Neuro)							
	Laparoscopic		L	<u> </u>				
	Pediatric				<u> </u>			
	Small Organ (Spec.)			<u> </u>		<u> </u>		
	Neonatal Cephalic				<u> </u>			
	Adult Cephalic		<u> </u>	<u> </u>				
	Trans-rectal	Ph	Ph	Ph	<u> </u>	Ph	Ph	Ph
	Trans-vaginal		<u> </u>	<u> </u>	1			
	Trans-urethral							
	Trans-esoph. (non-Card.)			<u> </u>				
	Musculo-skel. (Convent.)		ļ		↓		<u> </u>	
	Musculo-skel. (Superfic.)				<u> </u>			
	Intra-luminal		ļ		 			
	Other (spec.)		<u> </u>	<u> </u>				
·····	Cardiae Adult							
Cardiac	Cardiac Pediatric		<u> </u>					
	Trans-esophageal (card.)		L	<u> </u>	1		<u> </u>	
	Other (spec.)		<u> </u>					
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N = new indication. P = previously cleared in K110673

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "c": Includes imaging for guidance of trans-rectal biopsy
Subscript "f" Includes imaging for guidance of trans-vaginal biopsy

Subscript "g" For pediatric patients

Subscript "h" Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B, M, PWD, and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: UST-2265-2

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation D. M. L. P.W.D. L. C. Color L. Combined L. Others 1								
General (Track I only)	Specific (Tracks (& III)	13	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic		T								
-	Fetal										
Fetal Imaging	Abdominal										
& Other	Intra-operative (Spec.)										
	Intra-operative (Neuro.)						·				
	Laparoscopic		<u> </u>			_	<u> </u>				
	Pediatric				<u> </u>						
	Small Organ (Spec.)			ļ	↓		<u> </u>				
	Neonatal Cephalic			<u> </u>							
	Adult Cephalic			1	igsquare						
	Trans-rectal			<u> </u>	<u> </u>						
	Trans-vaginal		ļ	<u> </u>							
	Trans-urethral			<u> </u>							
	Trans-esoph. (non-Card.)										
	Musculo-skel (Convent.)			<u> </u>							
	Musculo-skel. (Superfic.)			↓							
	Intra-luminal			ļ	 _						
	Other (spec.)										
	Cardiac Adult			<u> </u>	P						
Cardiac	Cardiac Pediatric		↓	ļ		 	 				
	Trans-esophageal (card.)		↓	 	 						
	Other (spec.)				ll						
Peripheral	Peripheral vessel										
Vessel	Other (spec.)	· I		l			<u> </u>				

N = new indication P = previously cleared in K123R28

*Combination of each operating mode, B. M. PWD, CWD and Color Doppler

Additional Comments:

includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). Subscript "a":

Includes imaging of organs and structures exposed during surgery Subscript "b".

(excluding neurosurgery and laparoscopic procedures).

Includes thyroid, parathyroid, breast, scrotum, and penis. Subscript "c":

Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy. Subscript "d":

Includes imaging for guidance of trans-rectal biopsy Subscript "c": Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

For pediatric patients Subscript "g":

Includes imaging for guidance of trans-rectal hiopsy. Subscript "h":

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^{**}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elustography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: UST-5293-5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinic	cal Application			•	N	fode of Operation	1	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppfer	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
Fetal Imaging	Abdominal							
& Other	Intra-operative (Spec.)			<u> </u>				
	Intra-operative (Neuro)				<u> </u>			
	Laparoscopie							
	Pediatric		<u> </u>					
	Small Organ (Spec.)		<u> </u>		1			
	Neonatal Cephalic							· · · · · · · · · · · · · · · · · · ·
	Adult Cephalic			<u> </u>	$oldsymbol{ol}}}}}}}}}}}}}}}}}}$			
	Trans-rectal			<u> </u>	11			
	Trans-vaginal							
	Trans-urethral	<u> </u>						<u></u>
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)			1			<u> </u>	
	Cardiac Adult	P	P	þ	P	P	Р	p
Cardiac	Cardiac Pediatric						<u> </u>	ļ
	Trans-esophageal (card.)	Р	P	P	P	Р	Р	Р
	Other (spec.)		<u> </u>				<u></u>	
Peripheral	Peripheral vessel		l					ļ
Vessel	Other (spec.)			1				

N = new indication. P = previously cleared in K123828

Additional Comments:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis) Subscript "a":

Includes imaging of organs and structures exposed during surgery Subscript "b":

(excluding neurosurgery and laparoscopic procedures)

Includes thyroid, parathyroid, breast, scrotum, and penis Subscript "c"

Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy. Subscript "d"

Subscript "e" Includes imaging for guidance of trans-rectal biopsy Subscript "1" Includes imaging for guidance of trans-vaginal biopsy

Subscript "e" For pediatric patients

Subscript "h" Includes imaging for guidance of trans-rectal biopsy

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^{*}Combination of each operating mode, B. M. PWD, CWD and Color Doppler.

*Amplitude Doppler (Color Flow Angiography). Tissue Doppler Imaging

Device Name: Hitachi Arietta 70 / Arietta \$70 / Arietta \$70

Transducer: UST-52126

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec)			
Ophthalmic	Ophthalmic		1	1							
	Fetal										
Fetal Imaging	Abdominal										
& Other	Intru-operative (Spec.)			}							
	Intra-operative (Neuro.)			I							
	Laparoscopic			ł							
	Pediatric			1							
	Small Organ (Spec.)										
	Neonatal Cephalic]								
	Adult Cephalic			l							
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph (non-Card.)		<u> </u>				<u> </u>				
	Musculo-skel (Convent)		<u>l</u>								
	Musculo-skel (Superfic)		<u> </u>				<u> </u>				
	Intra-luminal										
	Other (spec.)										
	Cardiae Adult	. Р	P	P] P	p	Р	P			
Cardiac	Cardiac Pediatric						1				
	Trans-esophageal (card.)	Р	P	P	P	Р	Р	P			
	Other (spec.)			<u> </u>				<u> </u>			
Peripheral	Peripheral vessel										
Vessel	Other (spec.)			1				l			

N = new indication. P = previously cleared in K123828

Δdc	itiona	Con	rments

factudes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). Subscript "a":

Includes imaging of organs and structures exposed during surgery Subscript "b":

(excluding neurosurgery and laparoscopic procedures).

Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy Subscript "d":

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Includes imaging for guidance of trans-vaginal biopsy. Subscript "f":

For pediatric patients Subscript "g":

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B. M. PWD, CWD and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography). Tissue Doppler Imaging

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C4

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track I only)	Specific (Tracks I & 111)	ß	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic				II						
	Fetal										
Fetal Imaging	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa			
& Other	Intra-operative (Spec.)										
	Intra-operative (Neuro.)			Щ.			 				
	1.aparoscopic						_				
	Pediatric	Р	Р	Р		P	Р	P			
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd			
	Neonatal Cephalic				l						
	Adult Cephalic				<u> </u>						
	Trans-rectal				<u> </u>						
	Trans-vaginal			<u> </u>	<u> </u>						
	Trans-urethral			<u> </u>							
	Trans-esoph. (non-Card)										
	Musculo-skel. (Convent.)	P	Р	P		Р	P	P			
	Musculo-skel. (Superfic.)			.	<u> </u>						
	Intra-luminal			<u> </u>	1		<u> </u>				
	Other (spec.)		l	1							
	Cardiac Adult						ļ				
Cardiac	Cardiac Pediatric			ļ	ļ						
	Trans-esophageal (card.)			1			ļ				
	Other (spec.)			ł							
Peripheral	Peripheral vessel	P	Р	μ		P	Р	Р			
Vessel	Other (spec.)		l	1	l		1				

N = new indication P = previously cleared in K130308

Additional Comments.

Subscript "a": includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B. M. PWD and Color Doppler

^{**}Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C42

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	8	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophilialmic										
	Fetal										
Fetal Imaging	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa			
& Other	Intra-operative (Spec.)	₽b	Pb	Pb		Pb	Pb	Pb			
	Intra-operative (Neuro.)			1	<u> </u>		<u> </u>				
	Laparoscopic						<u> </u>				
	Pediatric	Р	P	p	 	P	P	P			
	Small Organ (Spec)	Pd	Pd	Pd		Pd	Pd	Pd			
	Neonatal Cephalic	Р	P	P		P	P	Р			
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal				<u> </u>						
	Trans-urethral	_1			 						
	Trans-esoph. (non-Card)				$oldsymbol{ol}}}}}}}}}}}}}}}}}$	·-··					
	Musculo-skel. (Convent.)										
	Musculo-skel. (Supertic.)			<u> </u>	<u> </u>						
	Intra-luminal			<u> </u>	1		ļ				
	Other (spec.)										
	Cardiac Adult										
Cardiac	Cardiac Pediatric			ļ <u>.</u>				_			
	Trans-esophageal (card.)			<u> </u>	<u> </u>		<u> </u>				
_	Other (spec.)			l							
Peripheral	Peripheral vessel	P	Р	p		Р	Р	P			
Vessel	Other (spec.)]	1 1		<u> </u>				

N = new indication. P = previously cleared in K130308

Additional Comments:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). Subscript "a"

Includes imaging of organs and structures exposed during surgery Subscript "b"

(excluding neurosurgery and laparoscopic procedures)

Includes thyroid, parathyroid, breast, scrotum, and penis, Subscript "c".

Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy. Subscript "d":

Includes imaging for guidance of trans-rectal biopsy Subscript "e": Includes imaging for guidance of trans-vaginal biopsy. Subscript "f":

For pediatric patients Subscript "g":

Includes imaging for guidance of trans-rectal biopsy. Subscript "h":

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^{*}Combination of each operating mode, B, M, PWD and Color Doppler

^{**}Amplitude Doppler (Color Flow Angiography), 3D imaging. Real Time Tissue Elastography, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C35

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic			Ì							
	Fetal	P	P	P	Р	P	Р	Р			
Fetal Imaging	Abdominal	P	P	Р	Р	Р	P	Р			
& Other	Intra-operative (Spec.)										
	Intra-operative (Neuro.)						1				
	Laparoscopic										
	Pediatric	Ρ	Р	P	Р	P	γ	P			
	Small Organ (Spec.)	Pc	Pc	Pc	Pc	Pe	Pc	Pc			
	Neonatal Cephalic			<u> </u>	<u> </u>						
	Adult Cephalic										
	Trans-rectal				11						
	Trans-vaginal										
	Trans-urethral				<u> </u>						
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)			1	1						
	Intra-luminal			<u> </u>	<u> </u>						
	Other (spec.)					_					
	Cardiac Adult										
Cordiac	Cardiac Pediatric						1				
	Trans-esophageal (card.)						<u></u>				
	Other (spec.)						<u> </u>				
Peripheral	Peripheral vessel										
Vessel	Other (spec.)						L				

N = new indication. P = previously cleared in K110673

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)
Subscript "b":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures)
Subscript "c"	Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e" Includes imaging for guidance of trans-rectal biopsy Subscript "f" Includes imaging for guidance of trans-vaginal biopsy

Subscript "g" For pediatric patients

Additional Comments:

Subscript "h" Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{*}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C22P

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	ral Application				N.	fode of Operation)	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	Р	р	μ		р	P	р
Fetal Imaging	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
& Other	Intra-operative (Spec.)							
	Intra-operative (Neuro.)					· ·		
	Laparoscopic							
	Pediatric	<u> </u>						
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic		<u> </u>	<u> </u>	<u> </u>			
	Trans-rectal							
	Trans-vaginal				<u> </u>			
	Trans-urethral				<u> </u>			
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)			<u> </u>			<u> </u>	
	Musculo-skel (Superfic.)			1			<u> </u>	
	Intra-luminal				<u> </u>			
	Other (spec.)			į				
	Cardiae Adult							
Cardiac	Cardiac Pediatric			<u> </u>				
	Trans-esophageal (card.)			ļ	 		<u> </u>	
	Other (spec.)		<u> </u>					
Peripheral	Peripheral vessel			Į			 -	
Vessel	Other (spec.)			1			L	

N = new indication. P = previously cleared in K110673

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c" Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy
Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B. M. PWD, and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C25P

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	cal Application					Mode of Operation	n	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Cotor Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
<u> </u>	Fcial	P	ГР	P		Р	p	Р
Fetal Imaging	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
& Other	Intra-operative (Spec.)			<u> </u>			'	
	Intra-operative (Neuro.)			<u> </u>			<u> </u>	
	Laparoscopic		L	<u> </u>			<u> </u>	
	Pediatric							
	Small Organ (Spec.)					<u> </u>		
	Neonatat Cephalic						J	
	Adult Cephalic		<u> </u>					
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral			<u> </u>	<u> </u>			
	Trans-esoph. (non-Card.)				<u> </u>			<u> </u>
	Musculo-skel. (Convent.)				<u> </u>		<u> </u>	
	Musculo-skel. (Superfic.)			<u> </u>				
	Intra-luminal						<u> </u>	
	Other (spec.)					<u> </u>		
	Cardiac Adult							
Cardiac	Cardiac Pediatric						<u> </u>	
	Trans-esophageal (card.)]					<u> </u>
	Other (spec.)				<u> </u>		<u> </u>	
Peripheral	Peripheral vessel			1				
Vessel	Other (spec.)							

N = new indication, P = previously cleared in K110673

Addit	ional	Comm	emis.

Subscript "d":

includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). Subscript "a":

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

includes thyroid, parathyroid, breast, scrotum, and penis. Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "1". includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Includes imaging for guidance of trans-rectal biopsy Subscript "h":

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cription Use Only (Per 21 CF)	R 801.109)	
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^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C41RP

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	cal Application				N	tode of Operation)	
General (Track I only)	Specific (Tracks 1 & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic			I				
	Fetal		[
Fetal Imaging	Abdominal							
& Other	Intra-operative (Spec.)		<u> </u>	<u> </u>				
	Intra-operative (Neuro.)				<u> </u>		<u> </u>	
	Laparoscopic			<u> </u>	<u> </u>			
	Pediatric							
	Small Organ (Spec.)		ľ					
	Neonstal Cephalic							
	Adult Cephalic		I					
	Trans-rectul			I				
	Trans-vaginal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-urethral	Pf	Pt	Pf		Pť	Pf	Pí
	Trans-esoph (non-Card)			<u> </u>				
	Muscuto-skel, (Convent.)		<u> </u>	<u> </u>	1			
	Musculo-skel. (Superfic.)			<u> </u>				
	Intra-luminal							
	Other (spec.)		}	<u> </u>			<u> </u>	
	Cardiac Adult			I				
Cardiac	Cardiac Pediatric					_		
	Trans-esophageal (card.)				I I		1	
	Other (spec.)		1					
Peripheral	Peripheral vessel							
Vessel	Other (spec.)				TI			

N = new indication. P = previously cleared in K123828

Additiona	Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures). Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy Subscript "d": Includes imaging for guidance of trans-rectal hispsy Subscript "e". Subscript "f": Includes imaging for guidance of trans-vaginal biopsy. Subscript "g": For pediatric patients Includes imaging for guidance of trans-rectal biopsy. Subscript "h":

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^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{••}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: C42K

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinic	al Application					fode of Operation	1	
General (Track I only)	Specific (Tracks I & III)	В	. M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	Fetal				[l
Fetal Imaging	Abdominal				-			
& Other	Intra-operative (Spec.)	РЬ	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic						· ·	
	Pediatric							
	Small Organ (Spec.)	PU	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	P	Р	P		P	P	Р
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal					· -		
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skel. (Convent.)			<u> </u>				
	Musculo-skel. (Superfic.)							ļ
	Intra-luminal		<u> </u>	ļ	<u> </u>		<u> </u>	
	Other (spec.)		<u> </u>	<u></u>				
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							<u> </u>
	Other (spec.)							<u> </u>
Peripheral	Peripheral vessel							
Vessel	Other (spec)				<u> </u>			

N = new indication. P = previously cleared in K130308

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy

Subscript "e": Includes imaging for guidance of trans-rectal hippsy Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h" Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B. M. PWD and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography)

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: L34

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinic	ral Application				M	ode of Operation)	
General (Track Lonly)	Specific (Trucks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic			Ī		_		
- - · · · · · · · · · · · · · · · · · ·	Fetal							
Fetal Imaging	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
& Other	Intra-operative (Spec.)							
	Intra-operative (Neuro.)			<u> </u>			1	
	Laparoscopic			<u> </u>			<u> </u>	
	Pediatric	P	Р	P	P	Р	Р	Р
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	<u>Pd</u>	Pd	Pd
	Neonaul Cephalic					·	<u> </u>	
	Adult Cephalic			ļ				
	Trans-rectal	i			<u> </u>			
	Trans-vaginal			1	<u> </u>		<u> </u>	
	Trans-urethral			1				
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	р	· р	P	Р	Р	Р	P
	Musculo-skel. (Superfic.)							
	Intra-luminal		<u> </u>	<u> </u>	11			
	Other (spec.)				l			
	Cardiac Adult							
Cardiac	Cardiac Pediatric			ļ	<u> </u>			
	Trans-esophageal (card.)			ļ	$oxed{igspace}$			
	Other (spec.)				<u> </u>			l
Peripheral	Peripheral vessel	р	P	P	р	Р	Р	Р
Vessel	Other (spec.)						1	

Additional Comments:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis) Subscript "a":

Includes imaging of organs and structures exposed during surgery Subscript "b"

(excluding neurosurgery and laparoscopic procedures)

Includes thyroid, parnthyroid, breast, scrotum, and penis Subscript "c"

Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy. Subscript "d"

Subscript "e" Includes imaging for guidance of trans-rectal biopsy

Includes imaging for guidance of trans-vaginal biopsy Subscript "F.

Subscript "g": For pediatric patients

Includes imaging for guidance of trans-rectal biopsy. Subscript "h":

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N = new indication. P = previously cleared in K130308
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging. Real Time Tissue Elastography, Real Time Virtual Sonography

Device Name: Ilitachi Arietta 70 / Arietta 870 / Arietta V70

Transducer: L441

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinic	al Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal									
Fetal Imaging	Abdominal									
& Other	Intra-operative (Spec.)						<u></u>			
	Intra-operative (Neuro.)									
	Laparoscopie		•							
	Pediatric									
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd		
	Neonatal Cephalic						<u> </u>			
	Adult Cephalic			<u> </u>			<u> </u>			
	Trans-rectal			1	1		<u> </u>			
	Trans-vaginal	1		1			<u> </u>			
	Trans-urethral				lacksquare					
	Trans-esoph. (non-Card.)			l			<u> </u>			
	Musculo-skel. (Convent.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd		
	Musculo-skel. (Superfic.)				<u> </u>			ļ		
	Intra-luminal			ļ			<u> </u>			
	Other (spec.)		_	•			1			
	Cardiac Adult			<u> </u>						
Cardiac	Cardiac Pediatric				1			 		
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel	Pd	Pd	Pd	Pd	Pd	Pd	Pd		
Vessel	Other (spec.)						<u> </u>			

N = new indication. P = previously cleared in K123828

Additional Comments:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis). Subscript "a":

Subscript "b":

Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c":

Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d":

Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e". Subscript "f": Includes imaging for guidance of trans-rectal hiopsy

Subscript "g":

Includes imaging for guidance of trans-vaginal biopsy.

For pediatric patients

Subscript "h"

Includes imaging for guidance of trans-rectal hiopsy.

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^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler

^{••} Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: 1.55

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinic	ral Application		Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec)	Other** (Spec.)			
Ophthalmic	Ophthalmic			<u></u>							
	Fetal			I							
Fetal Imaging	Abdominal	Pa	Pa	Ра	Pa	Pa	Pa	Pa			
& Other	Intra-operative (Spec.)										
	Intra-operative (Neuro.)			}							
	Laparoscopic		I								
	Pediatric	P	P	P	P	Р	P	P			
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd			
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal						ļ				
	Trans-urethral			<u> </u>			ļ				
	Trans-esoph. (non-Card.)		<u></u>								
	Musculo-skel. (Convent.)	P	Р	p	P	P	P	P			
	Musculo-skel. (Superfic.)	P	Р	P	P	Р	P	P			
	Intra-luminal		L <u>.</u>				<u> </u>				
	Other (spec.)		l]				
	Cardiac Adult										
Cardiac	Cardiac Pedintric										
	Trans-esophageal (card.)						ļ <u>.</u>				
	Other (spec.)						<u> </u>				
Peripheral	Peripheral vessel	P	P	P	P	Р	Р	P			
Vessel	Other (spec.)										

N = new indication, P = previously cleared in K130308

Additional Comments:

Subscript "a" Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c"

Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d":

Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy. Includes imaging for guidance of trans-rectal biopsy

Subscript "c"
Subscript "l"

Includes imaging for guidance of trans-vaginal biopsy

Subscript "g":

For pediatric patients

Subscript "h":

Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B, M, PWD, CWD, and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography),3D Imaging, Real Time Tissue Elastography, Real Time Virtual Sonography,

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: L46K

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	• м	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic		1							
	Fetal									
Fetal Imaging	Abdominal									
& Other	Intra-operative (Spec.)	Pb	Pb	Ph		Ph	Pb	Pb		
	Intra-operative (Neuro.)									
	Laparoscopic									
	Pediatric						<u> </u>			
	Small Organ (Spec.)									
	Neonatal Cephalic			ļ						
	Adult Cephalic									
	Trans-rectal		Ĭ				<u> </u>			
	Trans-vaginal						<u> </u>			
	Trans-urethral			1						
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)		<u> </u>							
	Intra-luminal			l						
	Other (spec.)				<u>l "l</u>					
	Cardiac Adult									
Cardine	Cardiac Pediatric			<u> </u>						
	Trans-esophageal (card.)									
•	Other (spec.)						<u> </u>			
Peripheral	Peripheral vessel									
Vessel	Other (spec.)					_		<u> </u>		

N = new indication. P = previously cleared in K123828

Additional Comments:

Subscript "a" Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)

Subscript "b" Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d": Includes thyroid, parnthyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e" Includes imaging for guidance of trans-rectal biopsy Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B. M. PWD, CWD and Color Doppler

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Virtual Sonography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: S31

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks 1 & 111)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic					· -				
	Fetal									
Fetal Imaging	Abdominal	Р	Р	P	P	P	P	Р		
& Other	Intra-operative (Spec.)									
	Intra-operative (Neuro.)									
	Laparoscopic		<u> </u>	1						
	Pediatric	Р	P	P	Р	Р	P	P		
	Small Organ (Spec.)		,							
	Neonatal Cephalic	Р	P	P	Р	Р	P	P		
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral						Ī			
	Trans-esoph (non-Card)			[
	Musculo-skel. (Convent.)		l							
	Musculo-skel. (Superfic.)				1		1			
	Intra-luminal]		I			
	Other (spec.)				l		<u></u>			
	Cardiac Adult	Р	Р	P	Р	P	p	P		
Cardiac	Cardiac Pediatric	P	Р	Р	Р	Р	Р	Р		
	Trans-esophageal (card.)									
	Other (spec.)				<u> </u>					
Peripheral	Peripheral vessel									
Vessel	Other (spec.)]			·	1			

N = new indication. P = previously cleared in K130308

Addi	tional	Com	ments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b" Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures)

Subscript "e" Includes thyroid, parathyroid, breast, scrotum, and penis

Subscript "d" Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy

Subscript "e" Includes imaging for guidance of trans-rectal biopsy

Subscript "f" Includes imaging for guidance of trans-vaginal biopsy

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography). Tissue Doppler Imaging

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: S31KP

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clini	Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	רן איין	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec)		
Ophthalmic	Ophthalmic					,				
	Fetal									
Fetal Imaging	Abdominal					<u> </u>				
& Other	Intra-operative (Spec.)									
	Intra-operative (Neuro.)	Pb	Pb	Pb	Pb	PЪ	Pb	Pb		
	Laparoscopic			1						
	Pediatric			L						
	Small Organ (Spec.)									
	Neonatal Cephalic									
	Adult Cephalic						<u> </u>			
	Trans-rectal									
	Trans-vaginal		<u> </u>	<u> </u>			<u> </u>			
	Trans-urethral									
	Trans-esoph. (non-Card.)			<u> </u>						
	Musculo-skel. (Convent.)						<u></u>			
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.)			<u> </u>						
	Cardiac Adult									
Cardiac	Cardiac Pediatric				ļ	·····				
	Trans-esophageal (card.)			<u> </u>						
	Other (spec)		<u> </u>				1			
Peripheral	Peripheral vessel									
Vessel	Other (spec.)	I]			l		

N = new indication. P = previously cleared in K123828

Additional	Comments

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy
Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h" Includes imaging for guidance of trans-rectal biopsy

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^{*}Combination of each operating mode, B. M. PWD, CWD and Color Doppler

^{**}Amplitude Doppler (Color Flow Angiography)

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer:

VL54

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Culur Dappler	Combined* (Spec.)	Other** (Spec)		
Ophthalmic	Ophthalmic				1					
	Fetal									
Fetal Imaging & Other	Abdominal	P	P	P		Р	P	Р		
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)									
	Laparoscopic					•				
	Pediatric	P	Р	Р		P	Р	Р		
	Small Organ (Spec.)	Pc	Pc	Pc	\perp	Pc	Pç	Pc		
	Neonatal Cephalic				<u> </u>					
	Adult Cephalic			<u> </u>				<u> </u>		
	Trans-rectal						<u> </u>			
	Trans-vaginal									
	Trans-urethral				$oxed{oxed}$					
	Trans-esoph. (non-Card.)		L	ļ <u> </u>	oxdot		ļ			
	Musculo-skel (Convent.)	Р	P	P		P	Р	P		
	Musculo-skel. (Superfic.)	Р	þ	P		Р	P	Ρ		
	Entra-lummal									
	Other (spec.)	<u> </u>					<u> </u>			
	Cardiac Adult									
Cardiac	Cardiac Pediatric					<u> </u>				
	Trans-esophageal (card.)		<u></u>	ļ	 		<u> </u>	<u> </u>		
	Other (spec.)			l						
Peripheral	Peripheral vessel	P	Р	P		þ	Р	Р		
Vessel	Other (spec.)	1	1	į.	1 1			l		

N = new indication. P = previously cleared in K110673

Additional Comments:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis) Subscript "a".

Subscript "b" includes imaging of organs and structures exposed during surgery

(excluding neurosurgery and laparoscopic procedures)

Includes thyroid, parathyroid, breast, scrotum, and penis Subscript "c"

Subscript 'd" Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e" Includes imaging for guidance of trans-rectal biopsy

Subscript "I": Includes imaging for guidance of trans-vaginal biopsy.

Subscript g": For pediatric patients

Includes imaging for guidance of trans-rectal biopsy. Subscript "h":

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^{*}Combination of each operating mode, B, M, PWD, and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Device Name: Hitachi Arietta 70 / Arietta S70 / Arietta V70

Transducer: UST-2266-5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Calor Doppler	Combined* (Spec.)	Other** (Spec.)		
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal						l			
	Abdominal						<u> </u>			
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)			<u> </u>						
	Laparoscopic			<u> </u>						
	Pediatric			<u> </u>						
	Small Organ (Spec.)				I					
	Neonatal Cephalic									
	Adult Cephalic		<u> </u>	<u> </u>						
	Trans-rectal									
	Trans-vaginal					·	<u> </u>			
	Trans-urethral			<u> </u>						
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)			1	oxdot					
	Intra-luminal		ļ	<u> </u>	<u> </u>					
	Other (spec.)			l						
	Cardiac Adult				Р					
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel				Р					
Vessel	Other (spec.)			1				l		

N = new indication. P = previously cleared in K123828

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

Additional Comments:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis) Subscript "a":

Includes imaging of organs and structures exposed during surgery Subscript "b":

(excluding neurosurgery and laparoscopic procedures).

Includes thyroid, parathyroid, breast, scrotum, and penis. Subscript "c":

Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy. Subscript "d":

Subscript "e": Includes imaging for guidance of trans-rectal biopsy Includes imaging for guidance of trans-vaginal biopsy. Subscript "Г":

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy

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^{••}Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Device Name: Hitachi Arietta 70 / Arietta \$70 / Arietta \$70

Transducer: UST-5418

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)			
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal			j	II]				
	Abdominal										
	Intra-operative (Spec.)	N	N	N		N	N	N			
	Intru-operative (Neuro.)										
	Laparoscopic	Р	P	Р		Р	Р	Р			
	Pediatric		<u> </u>								
	Small Organ (Spec.)			<u> </u>			<u> </u>				
	Neonatal Cephalic				<u> </u>						
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal			1							
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)						1				
	Musculo-skel, (Superfic.)										
	Intra-luminal				 						
	Other (spec.)			}							
	Cardiac Adult										
Cardiac	Cardiae Pediatric		1			···					
	Trans-esophageal (card)				1						
	Other (spec)										
Peripheral	Peripheral vessel										
Vessel	Other (spec.)		Ī								

N = new indication. P = previously cleared in K130308

Additional Com	
Subscript "a":	includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b":	Includes imaging of organs and structures exposed during surgery
-	(excluding neurosurgery and laparoscopic procedures).
Subscript "c":	Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript "d":	Includes thyroid, parathyroid, breust, scrotum, penis, and imaging for guidance of biopsy.
Subscript "e":	Includes imaging for guidance of trans-rectal biopsy
Subscript "I".	Includes imaging for guidance of trans-vaginal biopsy
Subscript "g":	For pediatric patients
Subscript "h":	Includes imaging for guidance of trans-rectal biopsy.
Prescription Use	Only (Per 21 CFR 801.109)

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^{*}Combination of each operating mode, B. M. PWD, and Color Doppler.

^{**}Amplitude Doppler (Color Flow Angiography), 3D Imaging, Real Time Tissue Elastography